

# Gearing up on NANO: Pharmatech for nanodrugs

**FR-JET TECHNOLOGY** Manufacturing of COVID vaccines showed that large-scale production of lipid nanoparticles (LNPs) as a delivery vehicle for mRNA vaccines is already possible. As nanocarrier-based formulations became mainstream, however, insufficiencies in existing technologies for routine GMP manufacturing became apparent. LEON is committed to bridging these technology gaps through its unique FR-JET technology and innovative manufacturing equipment.

**EuroBiotech** How accessible are LNPs for developing and manufacturing new therapeutic modalities?

**Dr Setu Kasera** The two most popular techniques used for lipid-based nanocarrier formulations are jet impingement and microfluidics, using mixing processes that operate in very different flow regimes. Jet impingement, which was the primary method used for making COVID vaccines, has clearly distinguished itself due to superior output of product volume. Yet, problems with the technique also persist, which need to be solved to enable its full utilisation. For example, finding the right process parameters to make nanoparticles with desired properties and quality currently is a tedious process, mostly based on trial-and-error. There can also be batch-to-batch variability and other issues with consistent particle quality. These issues can largely be attributed to poor mixer design.

The aim of LEON is to fully enable access to these nanocarrier-based formulations. Our FR-JET technology features a near-ideal mixer geometry constructed in a modular fashion, where different segments of the mixing system can be adjusted depending on client's needs. This design offers precise control over the process parameters and makes it possible to approach process development in a systematic manner. Importantly, the same mixer is used on the bench scale and commercial scale. This approach de-risks batch scale up and eliminates the need to invest



**Dr Setu Kasera** serves as chief scientific officer at leon-nanodrugs GmbH. With nearly a decade of hands-on experience in nanotechnology, she is directing research at LEON and is responsible for managing product development and data generation as well as strategic collaborations. She received her PhD in chemistry from the University of Cambridge, UK, followed by positions in research and business strategy in the biotech industry, with a focus on nanotechnology, drug development, CMC and science management.

time and resources for intermediate scale up and pilot equipment. Our devices are built especially for aseptic GMP-compliant manufacturing, featuring closed designs and using sterile single use components among others. Our NANOme® manufacturing device is a gamechanger, designed

such that batch changeover (including product changeover) takes less than a few minutes. Its operation is similar to inserting a cartridge into a printer and pressing a few buttons, bringing us much closer to making beside manufacturing a reality.

**EuroBiotech** How close is your product portfolio to maturity?

**Dr Setu Kasera** The development of our lab scale and GMP manufacturing equipment and their performance testing have been concluded successfully. We are now in the final stages of functional testing with industry partners. The benchtop NANOlab® device for process development and our small-scale GMP NANOme® device for on-site manufacturing are planned for market roll-out in 2024. We are already prospecting customers for our larger, high-volume GMP manufacturing device NANOus®, which has been designed in partnership with leading pharma production equipment manufacturer, Harro Höfliger.

**EuroBiotech** How do you enable access to your technology for potential clients?

**Dr Setu Kasera** Our pre-market benchtop units are already accessible for conducting feasibility projects in our laboratory in Munich. We can also ship the equipment to the client's site. Given the plug-and-play nature of our systems, installation and operations are not complicated and support from our expert team is available.